

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CITY OF HUNTINGTON

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

Civil Action No. 3:17-cv-01362

CABELL COUNTY COMMISSION,

Plaintiff,

v.

AMERISOURCEBERGEN DRUG
CORPORATION, et al.,

Defendants.

Consolidated Case:

Civil Action No. 3:17-cv-01665

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' RENEWED
DAUBERT MOTION TO EXCLUDE THE OPINIONS OF JAMES E. RAFALSKI

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Plaintiffs the City of Huntington and Cabell County Commission hereby submit this Memorandum of Law in Opposition to Defendants' Renewed *Daubert* Motion to Exclude the Opinions of James E. Rafalski (ECF No. 1385-1386).

Plaintiffs state in opposition to the renewed motion as follows.

INTRODUCTION

Mr. Rafalski is a former Drug Enforcement Agency ("DEA") diversion investigator with extensive law enforcement experience relating to the distribution of controlled substances under the Controlled Substances Act ("CSA"). Based on this experience, he has carefully assessed Defendants' Suspicious Order Monitoring ("SOM") programs and identified their serious flaws with regard to the maintenance of effective controls against diversion. He also has described and applied six different methodologies—two based on an approach endorsed by a United States Court of Appeals, and four based on systems Defendants and other distributors have used—that were available to Defendants to identify potentially suspicious orders that should not have been shipped without further diligence. He thus has provided valuable testimony on key disputed issues in this action.

While Defendants purport in their renewed motion to challenge the methodologies Mr. Rafalski used, they fail to identify any actual flaw in his methodologies and instead aim their fire at his conclusions, which they claim are "facially implausible." *See* Defendants' Memorandum of Law ("Defs' Memo") (ECF No. 1386) at 1. But Defendants' incredulity about Mr. Rafalski's conclusions is not a ground for exclusion. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 595

(1993) (“The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.”). This is exactly what Judge Polster concluded in rejecting the same arguments by Defendants and holding that any alleged over-inclusiveness of Mr. Rafalski’s opinions is a question of *weight* for the finder of fact to decide. *In re Nat’l Prescr. Opiate Litig.*, No. 1:17-md-2804, 2019 WL 3934490, at *6 (N.D. Ohio Aug. 20, 2019) (“*MDL Rafalski Op.*”) (“Defendants may argue to the jury that Rafalski’s method is over-inclusive and only the first order flagged as suspicious required due diligence, not every other order placed thereafter.”).

Defendants’ renewed challenges to Mr. Rafalski’s opinions also continue to mischaracterize both the opinions and the CSA’s applicable requirements. Defendants continue to conflate “suspicious orders,” a technical term with a defined meaning in the law (21 C.F.R. § 1301.74(b)), with orders that are likely to be diverted, a determination that can be made only after the due diligence Defendants failed to conduct. Mr. Rafalski offers opinions about the numbers of orders Defendants shipped that should have been flagged as “suspicious” under the law and should have triggered due diligence investigations, which Defendants never conducted. His opinions on the high percentage of suspicious orders that were shipped without appropriate due diligence show that Defendants did not have sufficient controls to prevent diversion (21 C.F.R. § 1301.71(a)), which predictably leads to large quantities of opioids being diverted to the illicit market.

Mr. Rafalski’s opinion that the failure to maintain effective controls caused diversion that actually occurred is neither controversial nor methodologically

flawed. Grounded in his experience as a DEA diversion investigator, this conclusion flows directly from his examination of Defendants' flawed SOM programs and their meager reporting of suspicious orders to the DEA.

Defendants' failure to perform their legal duties should not be used as a basis to deny the Court information about the numbers of suspicious orders Defendants should have identified and performed due diligence on before shipping. This is especially true because Mr. Rafalski does not purport to identify just a single method that all Defendants should have used. Rather, he opines about a range of SOM programs that Defendants might have used to satisfy their obligations with respect to detecting suspicious orders of unusual size, pattern, or frequency, and a range of numbers of orders that Defendants shipped in violation of their duties.

No greater precision is required, as it is not necessary for the Court as fact-finder to determine the exact number of such orders. Rather, the ranges Mr. Rafalski provided are relevant to the magnitude of the problem, to the likelihood of diversion, and to the connection between Defendants' failure to detect, report, and stop suspicious orders, and the diversion that in fact occurred. Defendants' arguments pose the untenable proposition that the more ways there are to identify suspicious orders, the less Plaintiffs should be allowed to provide evidence that Defendants failed to use any of them. But the Court need not proceed in the dark when multiple reliable methodologies exist to identify the suspicious orders Defendants failed to identify, investigate, or block. The renewed motion to exclude should be denied.

LEGAL STANDARD

In *Daubert, supra*, the Supreme Court provides an analytical framework for determining whether expert testimony is admissible under Fed. R. Evid. 702. Rule 702 provides that:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. *Daubert* provided a list of four non-exhaustive factors that a court may use in making its gatekeeping determination of reliability. *See* 509 U.S. at 593-94 (addressing ability to test, peer review and publication, known potential rate of error, and general acceptance within relevant community). These factors, however, are neither definitive nor exhaustive. *See Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 151 (1999) (*Daubert's* "factors do not all necessarily apply even in every instance in which the reliability of scientific testimony is challenged. It might not be surprising, in a particular case, for example, that a claim made by a scientific witness has never been the subject of peer review, for the particular application at issue may never previously have interested any scientist.").

The focus of the Court's inquiry under Rule 702 is the expert's methodology, not the conclusions reached. Noting that the "overarching subject" of the Rule 702 inquiry "is the scientific validity and thus the evidentiary relevance and reliability of the principles that underlie a proposed submission," the Supreme Court held in

Daubert that “[t]he focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.” 509 U.S. at 594-95. The Fourth Circuit has repeatedly echoed this caution. *See, e.g., Bresler v. Wilmington Trust Co.*, 855 F.3d 178, 195 (4th Cir. 2017) (“To determine whether an opinion of an expert witness satisfies *Daubert* scrutiny, courts may not evaluate the witness’s conclusion itself, but only the opinion’s underlying methodology.”); *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) (“The inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.”) (quoting *Daubert*, 509 U.S. at 1194-95).

Moreover, as this Court has recognized, *see* Trial Tr. (5/26/21) at 53:10-21, the facts on which an expert bases an opinion need not be in the record. The Rules of Evidence explicitly recognize this:

An expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed. If experts in the field would reasonably rely on those kinds of facts or data in forming an opinion on the subject, they need not be admissible for the opinion to be admitted.

Fed. R. Evid. 703; *see also Redman v. John D. Brush and Co.*, 111 F.3d 1174, 1179 (4th Cir. 1997) (“Federal Rule of Evidence 703 permits the admission of expert testimony even though the expert has relied on evidence that is inadmissible.”); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 722 (S.D. W. Va. 2014) (Rule 703 “allow[s] experts to rely on inadmissible evidence that is of the kind that is *reasonably* relied on by experts in the field.”) (emphasis in original).

Finally, the Fourth Circuit has repeatedly found the experience of law enforcement officials, including DEA agents, on the job to be a sufficient basis for them to offer expert opinion testimony. *See, e.g., United States v. Smith*, 919 F.3d 825, 835-36 (4th Cir. 2019) (“Courts have consistently approved of law enforcement agents like [FBI] Agent James offering expert interpretations of gang and drug communications based on their experience.”); *United States v. Fisher*, 662 Fed. Appx. 200, 202 (4th Cir. Oct. 7, 2016) (affirming admission of DEA agent’s opinion testimony on drug trade codes; recognizing that, “[i]n certain fields, experience is the predominant, if not the sole, basis for a great deal of reliable expert testimony.”) (quoting Fed. R. Evid. 702, 2000 advisory committee note).

ARGUMENT

I. Mr. Rafalski’s Methodologies for Identifying Suspicious Orders are Reliable.

Mr. Rafalski’s testimony addresses six methodologies that Defendants could have used to identify suspicious orders (Methods A-F). *See* Trial Tr. (5/26/21) at 84:20-85:17 (A-D), 93:22-95:21 (E-F). All of these methodologies are reliable bases for Mr. Rafalski’s opinions because they either have been accepted by a court reviewing DEA action against a distributor or else have been used by Defendants themselves and/or other distributors. Judge Polster addressed methods A and C-F and concluded that they are reliable in denying a motion to exclude Mr. Rafalski’s expert opinions:

As this Court has previously found, an order may be suspicious for any number of reasons, and there are many algorithms that a Distributor could use to identify orders as suspicious. Based on Rafalski’s extensive field experience as a DEA investigator reviewing the

effectiveness of Distributors' SOMS, the Court finds his expertise in identifying methodologies available to flag potentially suspicious orders is reliable. Moreover, in determining whether Defendants employed effective measures to identify, investigate, and stop shipment of suspicious orders, it would be helpful to the finder of fact to hear evidence about the number of suspicious orders that each methodology would have flagged. Accordingly, the Court concludes that Rafalski's methodologies are reliable and would aid the jury's determination of material issues in the case.

MDL Rafalski Op., 2019 WL 3934490, at *6 (citations omitted).

Nothing in Mr. Rafalski's testimony in this action changes these conclusions. Defendants try to suggest otherwise by arguing that he "conceded" that his six methodologies have not been applied in the real world. *See* Defs' Memo at 6. This is incorrect. Defendants reach this conclusion by conflating Mr. Rafalski's methodologies—which have been endorsed by a federal appeals court and/or used by Defendants themselves and other distributors—with his opinion that there is a lack of due diligence *in this case* based upon his review of these Defendants' records. *See id.* (Rafalski "was 'not aware of any company or regulator who has ever' applied the '[no]-due-diligence assumption to any set of data at any point in time.'"). Since the methodologies themselves have been used in the real world (*including by Defendants*) and the no-due diligence opinion in this case is supported by review of Defendants' records, Mr. Rafalski's application of both constitutes a reliable methodology.

Thus, each of Mr. Rafalski's six methodologies provides an appropriate basis for assessing the extent to which Defendants shipped opioids to Cabell County and the City of Huntington without performing the due diligence required by the CSA.

A. Methods A and B—Methods Based on Those Approved in *Masters* Case

1. Method A—*Maximum Monthly Trailing Six-Month Threshold*

Method A identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a calendar month to exceed the highest number of dosage units shipped by that distributor to that pharmacy in any one of the six preceding calendar months. *See* Trial Tr. (5/26/21) at 87:18-88:11. This methodology is described and endorsed by the court of appeals in *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017). *See* Trial Tr. (5/26/21) at 85:3-6.

Mr. Rafalski was the DEA’s lead diversion investigator in the *Masters* case. *See id.* at 22:3-13; *see also id.* at 22:20-25:3, 26:5-29:16 (describing investigatory work on *Masters* case). In *Masters*, the DEA revoked the registration of a distributor for failing in its duty to report suspicious orders, and the D.C. Circuit affirmed the revocation. *See* 861 F.3d at 211-12. The duty to report arises under 21 C.F.R. § 1301.74(b), which defines “[s]uspicious orders” to “include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

In assessing compliance, the court considered the distributor’s SOMS Computer Program, which flagged orders or sets of orders where:

- (a) that order—combined with other orders placed in the same 30-day period—requested more doses of a controlled medication than the pharmacy had requested in any of the previous six calendar months;
 - (b) the pharmacy ordered a controlled medication more frequently in a 30-day period than it had in any of the previous six calendar months;
- or

(c) the pharmacy's ordering pattern for a controlled medication deviated in some other notable way from its ordering pattern over the previous six months.

Id. at 216. The D.C. Circuit found that the above methodology identified suspicious orders of unusual size, pattern, or frequency because “[a]s a matter of common sense and ordinary language, orders that deviate from a six-month trend are an ‘unusual’ and not ‘normal’ occurrence.” *Id.* The court thus concluded that it was “entirely reasonable for the Administrator to hold that orders held by the Computer Program met the regulatory definition of ‘suspicious orders’ unless Masters’ staff dispelled the suspicion.” *Id.* at 216-17. The court further held that, without performing due diligence to dispel the suspicion, the distributor could not lawfully ship these flagged orders. *Id.* at 212-13, 221-22. The *Masters* decision thus demonstrates that Mr. Rafalski’s Method A—the *Maximum Monthly Trailing Six-Month Threshold*—is reliable as a means to identify suspicious orders. *See MDL Rafalski Op.*, 2019 WL 3934490, at *5 (citing *Masters* in holding *Maximum Monthly Trailing Six-Month Threshold* to be a “reasonable method for flagging orders that meet the regulatory definition of ‘suspicious orders’”).

In their renewed motion, Defendants ask the Court to disregard the foregoing based largely upon their disagreement with Mr. Rafalski’s *conclusions* reached from applying this methodology. They repeatedly attack as “implausible” his conclusions that over 90% of Defendants’ orders should have been flagged and then subject to due diligence or else not shipped. *See* Defs’ Memo at 1 (“facially implausible testimony”), 8 (“patently implausible testimony”), 12 (“facially implausible

assertion”), 21 (“implausible and manifestly unreliable results”), 25 (“facially implausible results”), 29 (“self-evidently implausible and unreliable results”).

The Court should reject these attacks as Judge Polster did explicitly and as the D.C. Circuit in *Masters* did implicitly in finding this to be a “common sense” methodology for measuring suspicious orders. As a preliminary matter, Defendants’ repeated attacks on Mr. Rafalski’s conclusions are not proper grounds for challenging the methodology he used to reach those conclusions. *See Bresler*, 855 F.3d at 195 (“To determine whether an opinion of an expert witness satisfies *Daubert* scrutiny, courts may not evaluate the witness’s conclusion itself, but only the opinion’s underlying methodology.”).

Digging more deeply, Defendants’ professions of shock that this methodology could result in over 90% of their orders being blocked reflect their disagreement with two elements of Mr. Rafalski’s expert analysis—(1) his opinion that Defendants did not perform adequate due diligence, *see* Trial Tr. (5/26/21) at 102:4-107:2; and (2) his opinion that subsequent orders cannot be shipped unless and until the suspicion giving rise to a flagged order is satisfactorily resolved, *see id.* at 89:3-9. Both of these opinions, however, are well-founded.¹

a. The No Adequate Due Diligence Opinion

The “no adequate due diligence” opinion is well supported by Mr. Rafalski’s careful review of Defendants’ customer files identified by Defendants in discovery.

¹ Although these opinions apply across all of Mr. Rafalski’s methodologies, Plaintiffs address them here in relation to Method A because this is the primary focus of Defendants’ motion. Plaintiffs’ arguments for the reliability of the opinions support their application to all of the methodologies.

See id. at 102:4-10 (review of Defendants’ due diligence and customer files); *id.* at 102:18-24 (review of Defendants’ suspicious order reporting). This review revealed both the absence of any evidence to dispel the suspicions that were or should have been flagged, *id.* at 102:14-17, and the presence of an absurdly low number of suspicious order reports actually made by Defendants. *See id.* at 103:3-24 (AmerisourceBergen—reported 45 orders out of 77,398 transactions from 2007 to 2018); *id.* at 104:14-105:16 (Cardinal Health—reported one (1) order out of 92,915 transactions from 1996 to 2011, and 291 orders from 2013 to 2017); *id.* at 105:17-106:1 (McKesson—reported zero (0) out of 18,862 transactions from 1996 to 2012, and 79 orders from 2013 to 2018).

Defendants attack Mr. Rafalski’s opinion that they did not perform due diligence as “*ipse dixit*.” *See* Defs’ Memo at 13-15 (“Mr. Rafalski attempted to justify his opinions by asserting that he did not see sufficient evidence of consumer-level diligence in the files that were produced by Defendants and made available to him. But his assumption that the absence of more complete customer files in Defendants’ litigation production means that no diligence was done is deeply flawed and contrary to the evidence.”). It is not.

This conclusion that the absence of documentation means an absence of due diligence is precisely the type of opinion that Mr. Rafalski’s experience as a DEA Diversion Investigator qualifies him to make. Judge Polster found this explicitly in rejecting the same argument by Defendants. *See MDL Rafalski Op.*, 2019 WL 3934490, at *6 (“Based on his experience as a DEA Diversion Investigator, however,

Rafalski may opine as to what the absence of due diligence records indicates to him.”). This conclusion finds further support in the D.C. Circuit’s *Masters* opinion:

As the Administrator noted, the lack of documentation was evidence that the [customer due diligence] phone calls never took place: ‘The *absence of an entry* [in business records], where an entry would naturally have been made if a transaction had occurred, should ordinarily be equivalent to an assertion that no such transaction occurred, and therefore should be admissible in evidence for that purpose.’

861 F.3d at 218 (quoting DEA Order (quoting 5 *Wigmore, Evidence* § 1531, at 463 (Chadbourn rev. 1974))) (emphasis in opinion).

Mr. Rafalski’s conclusion that the absence of documentation means an absence of due diligence is further supported by the documentation that did exist showing absurdly low levels of suspicious activity *reporting*. This type of evidence likewise was present and addressed by Judge Polster in his opinion finding Mr. Rafalski’s expert opinions admissible and his no due diligence opinion reasonable. *See MDL Rafalski Op.*, 2019 WL 3934490, at *6 (“Plaintiffs respond that Rafalski’s analysis is reliable because it is based on his extensive review of Defendants’ SOMS programs, after which he concluded that Defendants conducted little or no due diligence (*which is based, at least in part, on their failure to reports suspicious orders and/or document due diligence.*”) (emphasis added). Mr. Rafalski’s opinion that Defendants did not perform adequate due diligence on orders that should have been flagged thus is reasonable based on the evidence of record and on his extensive experience as a DEA Diversion Investigator.

b. The Subsequent Orders Opinion

Mr. Rafalski’s “subsequent orders” opinion likewise is reasonable. This opinion views a flagged order as triggering a “fire alarm” that is turned on and prohibits shipping further orders to a customer unless and until the flagged suspicion is satisfactorily resolved, which turns off the alarm and allows resumption of normal business. *See* Trial Tr. (5/26/21) at 89:3-9. This opinion is reasonable based upon *Defendants’ own use of this practice*, as well as both Mr. Rafalski’s own experience in this field and the governing law.

First, all three Defendants have used SOM programs that were designed to stop further shipments to customers until an order flagged as suspicious was resolved, just as Mr. Rafalski opines should be done. AmerisourceBergen’s Vice President of Corporate Security and Regulatory Affairs Chris Zimmerman agreed that the company’s OMP system was designed to do exactly this. *See* Trial Tr. (5/13/21) at 75:13-76:21 (“Q. This is an acknowledgement that if your OMP system flags an order as suspicious that you will cut off sales to that customer until you’ve resolved that suspicion. Agreed? A.. Yeah.”). Cardinal Health’s former Anti-Diversion section head Michael Mone likewise agreed that its SOM program implemented in 2007 was designed to terminate a customer’s further purchases of controlled substances until an order flagged as suspicious was resolved. *See* Trial Tr. (5/20/21) at 95:4-97:5 (“Q. The process laid out here has the customer being terminated from purchasing controlled substances or in totality; correct? A. That is the statement on the slide, yes.”). McKesson’s Controlled Substances Monitoring

Program (“CSMP”) says the same. *See* P-12627-00001 (McKesson Operations Manual) at bates page 2517 (“Upon escalation to Level 3, ALL controls will be blocked.”) (emphasis in original); P-42536_00001 (McKesson CSMP) at bates page 12 (“Any customer escalated to Level III[,] all controlled substances purchases blocked”). Defendants’ own embrace of this approach demonstrates that Mr. Rafalski’s “subsequent orders opinion” is reasonable.

Second, Judge Polster in the MDL also specifically addressed this opinion and found it reasonable based on Mr. Rafalski’s DEA investigatory experience. *See MDL Rafalski Op.*, 2019 WL 3934490, at *6 (quoting opinion that “any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern [about the customer]”) (quoting Report); *id.* (“Rafalski’s extensive experience investigating the effectiveness of Distributors’ SOMS provides a reasonable basis for this opinion.”).

The subsequent orders opinion also finds support from the DEA itself. *See Southwood Pharm., Inc.; Revocation of Registration*, 72 Fed. Reg. 36487-01,36500, 2019 WL 1886484 (DEA July 3, 2007) (“Indeed, it is especially appalling that notwithstanding the information Respondent received from both this agency and the pharmacies, it did not immediately stop distributing hydrocodone to any of the pharmacies.”); *see also id.* at 36501 (noting distributor’s failure to report pharmacy’s suspicious orders for months on end, after which “it distributed more than 2.1 million dosage units of hydrocodone” to the pharmacy).

Finally, in rejecting Defendants' challenge to Mr. Rafalski's subsequent order opinion, Judge Polster noted that "challenges to the accuracy of an expert's conclusions or factual basis generally bear on the weight of the evidence rather than its admissibility[.]" so that "Defendants may argue to the jury that Rafalski's method is over-inclusive and only the first order flagged as suspicious requires due diligence, not every other order placed thereafter." *MDL Rafalski Op.*, 2019 WL 3934490, at *6 (citation omitted).

This Court should hold the same, that Mr. Rafalski's subsequent orders opinion presents a question of weight, and not of admissibility, as to this or any of his methodologies or opinions.

2. **Method B-- Maximum Monthly Trailing Six-Month Threshold, Fixed After First Triggered Threshold**

Method B likewise identifies transactions that cause the number of dosage units shipped to a pharmacy in a month to exceed the highest number of dosage units shipped to that pharmacy in any one of the six preceding months. *See* Trial Tr. (5/26/21) at 89:10-14. When a transaction meeting these parameters is identified, the dosage units of the highest month in the preceding six months becomes the threshold, which is then applied in all subsequent months. *Id.* at 89:14-16.

This method is a slight variation on the *Masters* method employed in Method A. Like Method A, this method is based on the volume-based portion of the test set forth in *Masters*. *See* 861 F.3d at 206. While Method A compares the cumulative shipments in a drug code to the maximum of the trailing six calendar months and

once an order is flagged *all* subsequent orders are flagged, Method B does not take that last step. Instead, Method B applies the maximum of whatever the trailing six calendar months was at the time the first order was flagged and *establishes that as a threshold* and flags shipments on any day that would cause the cumulative total for that month to exceed this threshold and all additional orders the rest of the month that would exceed that threshold. *See* Trial Tr. (5/26/21) at 89:17-20.

Defendants challenge Method B on the same grounds on which they challenge Method A, *see* Defs' Memo at 22, 26, while they also highlight this sole methodological difference between them as an additional ground for exclusion. *See id.* at 26 ("Other than the flawed due-diligence assumption, Methods A and B share all of the flaws discussed above, and so Defendants' critiques apply equally to both. Moreover, the 400% error rate between Method A and Method B calls into question the reliability of both methodologies."). This argument is incorrect.

The concept of "error rate" addressed by the Supreme Court in *Daubert* does not apply to the difference in results generated by Mr. Rafalski's Methods A and B. In *Daubert*, the Supreme Court recognized that "*in the case of a particular scientific technique*, the court ordinarily should consider the known or potential rate of error." 509 U.S. at 594 (emphasis added). Mr. Rafalski's Methods A and B are not a single technique. They are two distinct techniques that have common features, but one key methodological difference. *See* Trial Tr. (5/26/21) at 226:21-26 ("A differs from B because B – the assumption in B is, is that a suspicious order is identified but yet, the shipping continues. The only difference is it's fixed after the first triggered

threshold . . .”). That this methodologically different approach yields a different result does not discredit either of the Methods at issue. *See, e.g., United States v. Smith*, 869 F.2d 348, 353-54 (7th Cir. 1989) (finding spectrographic voice identification reliable based on low error rates in studies, while also noting differences between error rates when testing conditions are changed).

The difference in outcome between Method A and Method B is one Judge Polster specifically identified as going to the former approach’s weight, not its reliability. *See MDL Rafalski Op.*, 2019 WL 3934490, at *6 (“Defendants may argue to the jury that Rafalski’s method is over-inclusive and only the first order flagged as suspicious requires due diligence, not every other order placed thereafter.”). This Court should hold the same. The methodological difference between Mr. Rafalski’s Methods A and B goes to their weight. Both are reliable and admissible.

B. Methods C Through F—Methods Based on Those Used by Defendants

1. Method C—Twice Trailing Twelve-Month Average Pharmacy Dosage Units

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a particular month to exceed twice the trailing twelve-month average dosage units to pharmacies served by the distributor. *See* Trial Tr. (5/26/21) at 92:3-93:12. This method is based on the SOM program used by Mallinckrodt PLC, an opioid and other prescription drug manufacturer. *See id.* at 85:12-14.²

² Since Defendants lump Methods C-F together for broad brush and inaccurate treatment in their renewed motion, *see* Defs’ Memo at 21, Plaintiffs briefly describe

2. Method D—Three Times Trailing Twelve-Month Average Pharmacy Dosage Units

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a calendar month to exceed three times the trailing twelve-month average dosage units to pharmacies served by the distributor. *See* Trial Tr. (5/26/21) at 93:13-21. This method is based on SOM programs that have been used by Defendants AmerisourceBergen and Cardinal Health. *See id.* at 85:15-17; *see also id.* at 61:23-62:6 (describing twelve-month national average determination).

These Defendants' use of the three times-monthly average approach is undisputed, as both companies' representatives acknowledged this. *See* Trial Tr. (5/13/21) at 53:14-59:10 (testimony of AmerisourceBergen Vice President of Corporate Security and Regulatory Affairs Chris Zimmerman) ("Q. 'The monthly average times factor for ARCOS items is presently set by DEA at three times the monthly average.' Do you see that? A. I do."); Trial Tr. (5/20/21) at 58:16-60:14 ("Q. For oxycodone and hydrocodone, did you triple the averages? A. For -- for Schedule II controlled substances, we took a multiplier of three.").

3. Method E—Maximum 8,000 Dosage Units Monthly

This method identifies transactions that cause the number of dosage units shipped by a distributor to a pharmacy in a calendar month to exceed 8,000 dosage units. *See* Trial Tr. (5/26/21) at 93:22-94:9. This method is based on a policy that

each of Methods C-F first and then address below Defendants' single argument as to them.

was used by Defendant McKesson Corporation beginning in or about May 2007, as McKesson's Director of Regulatory Affairs Michael Oriente confirmed. *See* Trial Tr. (5/24/21) at 31:23-32:3, 34:12-25 (8,000 dosage unit monthly threshold for oxycodone and for hydrocodone).

4. Method F—Maximum Daily Dosage Units

This method identified transactions shipped by a distributor to a pharmacy in a day to exceed a number of dosage units that varies by drug type and within some drug types by formulation. *See* Trial Tr. (5/26/21) at 94:20-95:21. This method is based on a policy put in place by Defendant Cardinal Health from the early 1990s until at least 2008. *See* Trial Tr. (5/26/21) at 57:23-58:11 (noting three iterations of Cardinal's SOM program); *see also* P-09320 (Cardinal Health's DEA Compliance Manual) at bates page 01383939) (describing policy).

5. Defendants' Challenge to Methods C Through F is Baseless.

Defendants attempt to brush off Mr. Rafalski's Methods C-F by claiming, incorrectly, that "Mr. Rafalski unequivocally disavowed [these] four of his six methodologies" on cross-examination. *See* Defs' Memo at 21. He did no such thing.

In the referenced cross-examination testimony, Mr. Rafalski answered a question seeking a qualitative comparison of his six methodologies as follows:

Q. Let's go through a few of them. Am I correct that when it comes to methodologies, C through F, you have not used those methods?

A. Well, it wouldn't be up to me to use or not. If – if you're asking me – if he's asking me, Your Honor, would I – if someone was to come to me and say should I used these methodologies, I'm not a DEA person anymore. I would tell them no and I would give them reasons why.

Q. Let me try it one more time. You would not use methods C through F, correct?

A. If I owned a company, a distributor, and I was going to design a suspicious order system, that's the basis for your question, that's correct, I would not use those.

Trial Tr. (5/26/21) at 224:25-225:12. This is not a “disavowal” of the validity of Methods C-F for at least two reasons.

First, Mr. Rafalski is careful to differentiate between his personal view as a potential business owner and the DEA's view, noting that he is not stating the latter (“I'm not a DEA person anymore.”). His answer thus says nothing about the validity of Methods C through F—each of which one or more Defendant or other distributor has used a version of—as methodologies for identifying suspicious orders. *See generally Palacino v. Beech Mt. Resort, Inc.*, No. 1:13-cv-334, 2015 WL 8675991, at *3 (W.D.N.C. Dec. 11, 2015) (finding expert opinions reliable where expert “formed his opinion based on his years of experience . . . and after reviewing numerous documents, industry publications, and industry standards.”).

Second, Mr. Rafalski's above statement is no different than his separate statement of preference for Method A over Method B. *See* Trial Tr. (5/26/21) at 219:10-24 (stating belief that result produced by Method A, as opposed to Method B, is correct). In both instances, he merely stated his personal preference for Method A, which was used in the *Masters* case, *see id.* at 85:3-6; *see also Masters*, 861 F.3d at 216-17 (“As a matter of common sense and ordinary language, orders that deviate from a six-month trend are an ‘unusual’ and not ‘normal’ occurrence.”), on which he was DEA's Lead Diversion Investigator. Trial Tr. 22:9-13.

Defendants do not and cannot contend that Mr. Rafalski also “disavowed” Method B because he did not. Just the opposite, he expressly disavowed disavowing the validity of *any* of his methodologies. *See id.* at 82:15-17 (“Q. Mr. Rafalski, is there one particular golden rule on what the trigger should be? A. No, Your Honor.”); *see also MDL Rafalski Op.*, 2019 WL 3934490, at *6 (“[A]n order may be suspicious for any number of reasons, and there are many algorithms that a Distributor could use to identify opioid orders as suspicious.”). Defendants thus present no basis for exclusion of Mr. Rafalski’s Methods C through F.

C. Defendants’ Remaining Arguments for Exclusion of Mr. Rafalski’s Six Methodologies are Likewise Baseless.

Defendants’ remaining arguments for exclusion of Mr. Rafalski’s six methodologies largely repeat their previously unsuccessful arguments. For example, Defendants contend that the methodologies are unreliable under *Daubert* because they allegedly have not been tested. *See* Defs’ Memo at 27. Judge Polster addressed and rejected this exact argument in the MDL:

Defendants argue the five methodologies are unreliable because Rafalski has not tested the results to determine, if, in fact, they flagged orders that were actually suspicious. In response, Plaintiffs point out that some Defendants actually used Rafalski’s methods in their own SOMS, and the D.C. Circuit has endorsed the ‘Maximum Monthly, Trailing 6-Month Threshold’ as a reasonable method for flagging orders that meet the regulatory definition of ‘suspicious orders.’

. . . Based on Rafalski’s extensive field experience as a DEA investigator reviewing the effectiveness of Distributors’ SOMS, the Court finds his expertise in identifying methodologies available to flag potentially suspicious orders is reliable.

MDL Rafalski Op., 2019 WL 3934490, at *6.

This also suffices to answer Defendants’ separate criticism that these methodologies were created for litigation, have not been subject to peer review, and/or lack general acceptance. *See* Defs’ Memo at 27-28. The fact that they have been used by prescription drug distributors and the DEA and endorsed by a federal appeals court in affirming the results of a DEA investigation is more peer review and acceptance in this setting than Rule 702 could ever reasonably require. *See Daubert*, 509 U.S. at 594-95 (“The inquiry envisioned by Rule 702, we emphasize, is a flexible one.”).³

For all of the foregoing reasons, the Court should reject Defendants’ renewed challenges to Mr. Rafalski’s methodologies for identifying suspicious orders.

II. Mr. Rafalski’s Diversion Causation Opinions are Reliable.

The Court also should reject Defendants’ arguments for exclusion of Mr. Rafalski’s separate opinions pertaining to causation of diversion. He testified that

³ *See also Wiener v. AXA Eq. Life Ins. Co.*, 481 F. Supp. 3d 551, 559 (W.D.N.C. 2020) (“The flexibility of the district court’s reliability assessment is particularly applicable when expert testimony is based on experience, ‘as there exist meaningful differences between how reliability must be examined with respect to expert testimony that is primarily experiential in nature as opposed to scientific.’”) (quoting *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007)); *Funderburk v. S.C. Elec. & Gas Co.*, 395 F. Supp. 3d 695, 723 (D.S.C. 2019) (“While this type of opinion is obviously not subject to peer review or testing, it is sufficient for Mr. Cometto to draw upon his professional experience and review of a range of local, state, and federal guidelines for him to reach this particular . . . opinion”); *id.* (“The plaintiff argues that the defendants’ criticism of King’s ‘methodology’ is misplaced since her opinions are based on specialized knowledge and experience rather than scientific evaluation. This court agrees. The factors listed in *Daubert* do not constitute a definitive checklist or test, and ‘the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.’”) (quoting *Kumho*, 526 U.S. at 152).

Defendants' systemic failures to maintain effective controls to prevent diversion were a substantial factor in the diversion of prescription opioids into the illicit market in Cabell County and the City of Huntington. *See* Trial Tr. (5/26/21) at 111:19-112:2. He further testified that the orders Defendants knew or should have known were suspicious were likely to be diverted into the illicit market in Cabell County and the City of Huntington. *See id.* at 112:22-113:6.

Defendants here again contend that Mr. Rafalski has not established a reliable methodology underlying these opinions. *See* Defs' Memo at 9. This, too, is incorrect. Mr. Rafalski's opinions regarding the likelihood of diversion are based on his own background and experience as a DEA Diversion Investigator and on his extensive review of Defendants' documents and conduct as an expert in this matter. *See, e.g., American Auto Ins. Co. v. Omega Flex, Inc.*, 783 F.3d 720, 726 (8th Cir. 2015) ("Dr. Kytomaa's extensive credentials qualified him as an expert in fire causation. He based his opinions on that experience and his examination of the fire scene and the TracPipe involved."); *Cisson v. C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 627 (S.D. W. Va. 2013) (gynecologist's "significant experience" with pelvic mesh products and examining patients with mesh complications qualifies him to offer causation opinions); *Wagoner v. Exxon Mobil Corp.*, 813 F. Supp. 2d 771, 800 (E.D. La. 2011) ("Dr. Butler's aforementioned education and work experience make her qualified to provide an opinion on general causation.").

These opinions also are consistent with the DEA's longstanding positions. The DEA Diversion Investigator's manual states that where suspicious orders are

placed “over extend periods of time, [this] would lead a reasonable person to believe that controlled substances possibly are being diverted.” P-09307 (DEA Diversion Manual) at bates page 01176301. They also are consistent with the DEA’s opinion in the *Southwood* matter, where the agency concluded that “the direct and foreseeable consequence of the manner in which Respondent conducted its due diligence program was *the likely diversion of millions of dosage units of hydrocodone.*” *Southwood Pharm., Inc.; Revocation Order, supra*, 72 Fed. Reg. at 36501 (emphasis added).

Indeed, Congress too recognizes that the very purpose of requiring that “distributors identify, report, and stop suspicious orders of opioids” is to “reduce diversion rates.” Public Law 115-271, § 3272(a); *see also City and County of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 680 (N.D. Cal. 2020) (“The very existence of the duties to maintain effective controls supports the notion that opioid misuse is foreseeable. ‘A lack of reasonable care in the handling, distribution, and administration of controlled substances can foreseeably harm the individuals who take them. *That’s why they’re ‘controlled’ in the first place*”) (quoting *Dent v. NFL*, 902 F.3d 1109, 1119 (9th Cir. 2018)) (emphasis added).

In sum, Mr. Rafalski’s extensive experience as a DEA Diversion Investigator and his immersion therein and herein in Defendants’ documents and conduct provide strong qualification and foundation for him to provide the anything-but-controversial opinion that Defendants’ failures to maintain effective controls against diversion caused diversion.

CONCLUSION

For all of the reasons set forth, the Court should deny Defendants' renewed motion to exclude Mr. Rafalski's expert opinions.

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Respectfully submitted,

THE CITY OF HUNTINGTON

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CERTIFICATE OF SERVICE

I certify that on June 3, 2021, a copy of the foregoing was filed electronically. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system.

/s/ Anthony J. Majestro